



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket Nos. 71369.368 and PFI-016CIPDV)

In re Application of: Orlow et al. ) Examiner: To Be Assigned  
Serial No. 10/758,335 ) Group Art Unit: To Be Assigned  
Filing Date: January 15, 2004 )

For: METHODS AND COMPOSITIONS THAT AFFECT MELANOGENESIS

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**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 CFR §1.8**

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Date: 2/18/04

Sarah Farris  
Sarah Farris

\*\*\*\*\*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Dear Sir:

Enclosed for filing in the above-identified patent application are the following documents:

1. Information Disclosure Statement (2 pages);
2. Forms PTO-1449 Copied From Parent Application (09/827,428);
3. Forms PTO-892 Copied From Parent Application (09/827,428);
4. Certificate of First Class Mailing; and
5. Return Postcard.

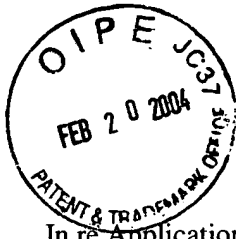
No fees are believed to be due in connection with this submission. However, please charge any fees that might be due or credit any overpayment to our Deposit Account No. 08-0219.

If there are any questions, please call the undersigned at the number below.

Respectfully submitted,

Date: 2/18/04  
HALE AND DORR LLP  
60 State Street  
Boston, MA 02109  
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Ann-Louise Kerner  
Ann-Louise Kerner, Ph.D.  
Reg. No. 33,523  
Attorney/Agent for Applicants



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P.O. Box 1450  
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**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R., Applicants submit herewith the attached Forms PTO-1449 and Forms PTO-892 for filing in the above-referenced application. The present application is a divisional of U.S. Patent Application No. 09/827,428. The Forms PTO-1449 and Forms PTO-892 attached herewith list references that were already submitted by the Applicants in the parent application; therefore, pursuant to 37 C.F.R. § 1.98 (d), no copies of the previously cited art are enclosed. This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97 (b) before the mailing date of the first Office Action, therefore no fee is believed to be due.

This submission does not represent that a search has been made and does not constitute an admission that the listed documents are material to the patentability of the invention, or that the listed documents are prior art. Applicant reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application. If it should be determined that any of the listed documents constitute prior art under United States law, Applicant reserves the right to present to the Office relevant facts and law regarding the significance of such documents to the patentability of the claimed invention.

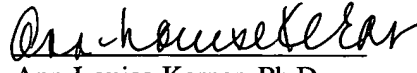
It is respectfully requested that the Examiner initial each reference listed on the attached Forms PTO-1449 and Forms PTO-892 and return same with the next Patent Office communication.

U.S. Patent Application No. 10/758,335  
Information Disclosure Statement  
Page Two

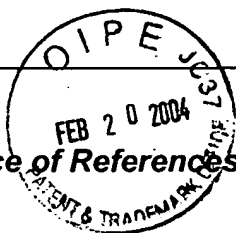
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Ann-Louise Kerner, Ph.D.  
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Attorney/Agent for Applicants

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Application/Control No.

09/827,428

Applicant(s)/Patent Under  
Reexamination  
ORLOW ET AL.

Examiner

Rebecca Cook

Art Unit

1614

Page 1 of 2

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
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	N					
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**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	MEDLINE AN 1998010047, Sabroe et al, Br. J. Dermatol. 1997 Sept 137 (3) 386-90, abstract.
	V	CA129:347178, Lambers et al, WO 9849999, 19981112, abstract.
	W	CA129:184644, Hermsmeyer, WO 9837897, 19980903, abstract.
	X	CA117:239545, Szycher et al, High Perform. Biomater. 1991, 807-12, abstract.

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

**Notice of References Cited**

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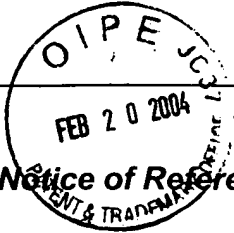
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	U	CA50:17370, Cohen et al, Psychiat. Res. Repts 1955, No. 1 11-13, abstract.
	V	Webster's II New Riverside University Dictionary, 1984, p.96, p. 762.
	W	
	X	

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<b>Application/Control No.</b> 09/827,428	<b>Applicant(s)/Patent Under Reexamination</b> ORLOW ET AL.	
	<b>Examiner</b> Rebecca Cook	<b>Art Unit</b> 1614

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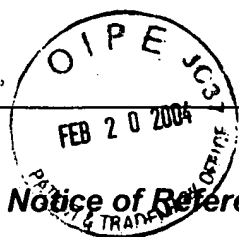
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	V	MEDLINE 67014260, Gibbard, Am. J. Psychiatry, 1966 Sep 123(3) 351-2, abstract.
	W	CA130:295103, Patel, Proceedings Nat. Acad. Sc.USA, 1999, 96(4) 1657-1662, abstract.
	X	CA126:190 Hashizume et al, JP 08337528 A2, Dec.1996, abstract.

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	U	EMBASE 1998386460, Bayer et al, J. Virology, 1998 72/12 9645-9655, abstract.
	V	
	W	
	X	

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Subt. For, PTO-1449				Docket Number 71369.162US3		Application Number 09/827,428	
INFORMATION DISCLOSURE IN AN APPLICATION  (Use several sheets if necessary)				Applicant Orlow et al.			
				Filing Date April 6, 2001		Group Art Unit 1614	
Sheet	1	OF	1				

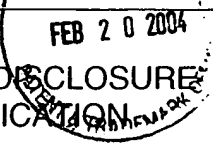
U.S. Patent Documents						
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,993,835	Nov 30, 1999	Mishima	424	401	Apr 14, 1998

Foreign Patent Documents							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)		

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Subt. For, PTO-1449  <b>INFORMATION DISCLOSURE IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>				Docket Nos. <b>71369.162 and PFI-016CIP</b>		Appln. No. <b>09/827,428</b>	
				Applicant <b>Hall et al.</b>			
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Filing Date <b>April 6, 2001</b>		Group Art Unit <b>1645</b>					
Sheet	1	OF	10				

U.S. Patent Documents						
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	5,232,917	Aug 3, 1993	Bolger et al.	514	176	Aug 13, 1991
	5,011,681	Apr 30, 1991	Ciotti et al.	424	81	Oct 11, 1989
	4,421,769	Dec 20, 1983	Dixon et al.	424	358	Sep 29, 1981
	3,755,560	Aug 28, 1973	Dickert et al.	424	78	June 30, 1971
	5,073,371	Dec 17, 1991	Turner et al.	424	401	Nov 30, 1990
	5,073,372	Dec 17, 1991	Turner et al.	424	401	Nov 30, 1990
	5,151,209	Sep 29, 1992	McCall et al.	252	174	Feb 8, 1991
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	5,120,532	Jun 9, 1992	Wells et al.	424	70	Apr 6, 1990
	4,387,090	Jun 7, 1983	Bolich Jr.	424	70	Feb 13, 1981

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						YES	NO
	WO 00/58549	Oct 5, 2000	PCT				
	WO 88/09810	Dec 15, 1988	PCT				
	WO 90/11364	Oct 4, 1990	PCT				
	WO 99/09011	Feb 25, 1999	PCT				
	WO 99/64025	Dec 16, 1999	PCT				
	WO 00/62742	Oct 26, 2000	PCT				
	WO 99/56740	Nov 11, 1999	PCT				
	WO 00/76473	Dec 21, 2000	PCT				
	WO 00/56702	Sep 28, 2000	PCT				
	WO 99/64025	Dec 16, 2000	PCT				

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)		
A1		Riley, "Molecules in Focus," Int. J. Biochem. Cell Biol., Vol. 29, No. 11, pp1235-1239
A2		Sidman et al., "Pink Eyed Dilution (p) Gene in Rodents: Increased Pigmentation in Tissue Culture," Developmental Biology, Vol. 12, 1985, pp 93-116
A3		Shirota et al., "Tyrosinase Inhibitors from Crude Drugs," Biol. Pharm. Bull. Vol. 17, No. 2, pp 266-269
A4		Tasaka et al., "Effects of Certain Resorcinol Derivatives on the Tyrosinase Activity and the Growth of Melanoma Cells," Meth. Find Exp. Clin. Pharmacol., 1998, Vol. 20, No. 2, pp 99-109
A5		Reish et al., "Tyrosinase Inhibition Due to Interaction of Homocyst(e)ine with Copper," Am. J. Hum. Genet. 1995, Vol. 57, pp 127-132

EXAMINER	DATE CONSIDERED
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Subt. For, PTO-1449				Docket Nos. 71369.162 and PFI-016CIP		Appln. No. 09/827,428	
INFORMATION DISCLOSURE IN AN APPLICATION  (Use several sheets if necessary)				Applicant Hall et al.			
				Filing Date April 6, 2001		Group Art Unit 1645	
Sheet	2	OF	10				

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## U.S. Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	3,155,591	Nov 3, 1964	Hilfer et al.	167	87	Dec 6, 1961
	3,929,678	Dec 30, 1975	Laughlin et al.	252	526	Aug 1, 1974
	5,691,380	Nov 25, 1997	Mason et al.	514	562	Jun 29, 1995
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	4,959,393	Sep 25, 1990	Torihara et al.	514	724	Apr 27, 1989
	5,580,549	Dec 3, 1996	Fukuda et al.	424	62	Mar 16, 1995
	6,123,959	Sep 26, 2000	Jones et al.	424	450	Apr 24, 1998
	6,132,740	Oct 17, 2000	Hu	424	401	Sep 15, 1998

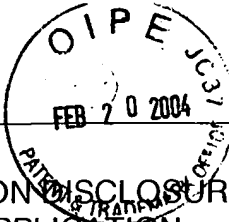
## Foreign Patent Documents

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
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	WO 99/32077	Jul 1, 1999	PCT				
	EP 0 993 826 B1	Apr 19, 2000	EP				
	EP 0 993 826 A1	Apr 19, 2000	EP				
	EP 0 997 140 B1	May 3, 2000	EP				
	EP 0 997 140 A1	Oct 12, 1998	EP				

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A6	Iida et al., "Potent Inhibitors of Tyrosinase Activity and Melanin," Planta Med., Vol. 61, 1995, pp 425-428
A7	Russell, "Quantitative Histological Study of the Pigment Found in the Coat Color of Mutants of the House Mouse," Genetics, Vol. 34, 1949, pp 146-166
A8	Swift et al., "Tissue Specific Expression of the Rat Pancreatic Elastase Gene in Transgenic Mice," Cell, Vol. 38, 1984, pp 639-646
A9	Manga et al., "The Pink Eyed Dilution Gene and the Molecular Pathogenesis of Tyrosinase-Positive Albinism," Journal of Dermatology, Vol. 26, 1999, pp 738-747
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A11	Hammer et al., "Diversity of Alpha-Fetoprotein Gene Expression in Mice..." Research Articles, Vol. 235, 1987 pp 53-58
A12	Villa-Komaroff et al., "A Bacterial Clone Synthesizing Proinsulin," Proc. Natl. Acad. Sci., Vol. 75, No. 8, pp 3727-3731
A13	Van der Krol et al., "Modulation of Eukaryotic Gene Expression by Complementary RNA or DNA Sequences," BioTechniques, Vol. 6, No. 10, 1998 pp 958-976

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Sheet	3	OF	10	Group Art Unit 1645			

U.S. Patent Documents						
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	6,132,740	Oct 17, 2000	Hu	424	401	Sep 15, 1998
	6,159,482	Dec 12, 2000	Tuloup et al.	424	401	Aug 26, 1998
	4,278,656	Jul 14, 1981	Nagai et al.	424	62	Jul 18, 1979
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	3,210,386	Oct 5, 1965	Birkenmeyer et al.	260	397.3	Jan 9, 1961
	5,627,033	May 6, 1997	Smith et al.	435	6	Mar 28, 1995
	5,681,744	Oct 28, 1997	Greenstein	435	320.1	May 17, 1995
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Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)		
A14	Brinster et al., "Regulation of Metallothionein-thymidine Kinsase Fusion Plasmids Injected into Mouse Eggs," Nature, Vol. 296, 1982, pp 39-42	
A15	Benoist et al., "In Vivo Sequence Requirements of the SV40 Early Promoter Region," Nature, Vol. 290, 1981, pp 304-310	
A16	Chang et al., "Rat Gene Encoding the 78-kDa Glucose-Regulated Protein GRP78," Proc. Natl. Acad. Sci., Vol. 84, 1987, pp 680-684	
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A18	Gautier et al., "DNA IV: enomeric and $\beta$ -anomeric Tetrathymidylates..." Nucleic Acids Research, Vol. 15, No. 16, 1987, pp 6625-6641	
A19	Gilbert et al., "Useful Proteins from Recombinant Bacteria," pp 74-94	
A20	Gossen et al., "Transcriptional Activation by Tetracyclines in Mammalian Cells," Science, Vol. 268, 1995, pp 1766-1769	
A21	Rinchik et al., "A Gene for the Mouse Pink-Eyed Dilution Locus..." Nature, Vol. 361, 1993, pp 72-76	

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Sheet	4	OF	10			Group Art Unit 1645	

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	5,389,611	Feb 14, 1995	Tomita et al.	514	6	Dec 9, 1991
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	5,849,997	Dec 15, 1998	Grosveld et al.	800	2	Jun 7, 1995
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	5,665,578	Sep 9, 1997	Gillies	435	172.3	Apr 5, 1994
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	5,302,517	Apr 12, 1994	Rhode, III	435	69.1	Mar 20, 1992
	4,959,313	Sep 25, 1990	Taketo	435	69.1	Jan 22, 1987

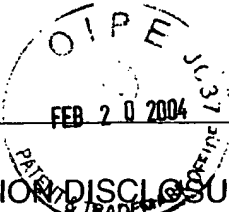
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						YES	NO

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A22	Grosschedi et al., "Introduction of a u-Immunoglobulin Gene into the Mouse Germ Line..." Cell, Vol. 38, 1984, pp 647-658
A23	Stein et al., "Physicochemical Properties of Phosphorothioate Oligodeoxynucleotides," Nucleic Acids Research, Vol. 16, No. 8, 1988 pp 3209-3221
A24	MacDonald, "Expression of the Pancreatic Elastase I Gene in Transgenic Mice," Hepatology, Vol. 7, No. 1, pp 42S-51S
A25	Kromberg, "Albinism and Skin Cancer in Southern Africa," Clinical Genetics, Vol. 36, 1989, pp 43-52
A26	Shani, "Tissue-specific Expression of Rat Myosin Light-Chain 2 Gene in Transgenic Mice," Nature, Vol. 314, 1985
A27	Letsinger et al., "Cholesteryl-conjugated Oligonucleotides: Synthesis, Properties, and Activity..." Proc. Natl. Acad. Sci., Vol. 86, pp 6553-6556
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A29	Hanahan, "Heritable formation of Pancreatic $\beta$ -cell Tumors in Transgenic Mice Expressing Recombinant Insulin/Simian Virus 40 Oncogenes," Nature, Vol. 315, 1985, pp 115-122

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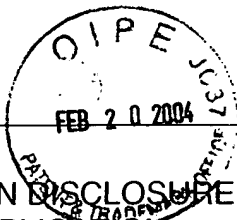
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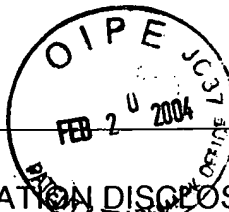
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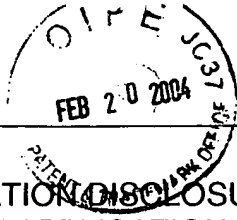
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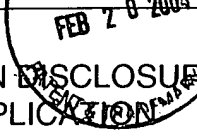
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